K961611

JUL 18 1996

510(k) SUMMARY FOR OLYMPUS FG BASKET GRASPING FORCEPS

Device Name:

Olympus FG-16/17/18/19/22/23/24-1 Grasping Forceps

(Urology)

Common/Usual Name:

Basket Graspers

Classification Name:

Endoscope and Accessories 21 CFR 876.1500, Class II

Predicate Device:

Olympus pre-Amendment and 510(k) cleared grasping forceps

Olympus FG Basket Grasper Forceps (K955063)

Contact Person:

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Summary Preparation Date:

March 18, 1996

Statement of Intended Use:

The Olympus basket graspers are intended to be used to retrieve

foreign bodies, excised tissue, etc., endoscopically.

Device Description:

The Olympus basket graspers are designed to retrieving foreign body, excised tissue, etc., under endoscopic visualization. These forceps consist of a flexible shaft and a proximal control handle. Operation of the proximal control handle actuates the

grasping basket.